

# **EXHIBIT C**

PATENT  
B0033/7001C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re The Application of: Stephen A. Raymond et al.

Serial No. 09/001,032

Filed: December 30, 1997

For: HEALTH MONITORING SYSTEM

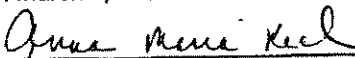
Examiner: Not yet assigned

Art Unit: 3737

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CERTIFICATE OF MAILING

I hereby certify that the following Preliminary Amendment is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on March 1, 1999.

  
Anna Maria Keel

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

**AMENDMENT A**

The following is responsive to the office action dated September 29, 1998. Applicants respectfully request a two-month extension for the filing of this response. A petition and appropriate fee are being filed concurrently herewith.

Please amend the application as follows:

PHT 000475

PHTeTRIALS000476

In the Claims

Please cancel Claims 11-26 and 32-34.

Please amend the claims as follows:

1. (Amended) A portable personal health tracker comprising:

a [portable,] multiparametric physiological monitoring device which periodically and automatically measures and records from a subject a plurality of different physiological data pertinent to a plurality of different physiological systems[, said different physiological data being collected as an ensemble of measurements taken over time, said ensemble of measurements not being directed to any particular medical condition of the subject but being indicative of a variety of trends in the subject's health such as to describe a general state of health of the subject];

a time base which tracks the time of recording of the physiological data;

a data storage unit in which the physiological data is stored with reference to the time base such as to provide a chronological health history of the subject [which covers a period of time that includes time periods during which the subject is in substantially good health and those during which the subject is subject to adverse medical conditions]; [and]

a data logger which collects subjective data from the subject regarding the subject's psychological condition and subjectively observed physiological condition; and

a data transmission device capable of connecting directly to a communication network to allow transmission of data to a destination site from points of access to the network that are remote to the destination site, wherein each of the components of the health tracker is part of a single, unified portable unit that may be used by an ambulatory patient.

8. (Amended) A personal health tracker according to Claim 1 further comprising a message receiving [means] apparatus by which the subject may view messages directed to the [data logger from the data storage unit] health tracker via the communication network.
  
9. (Amended) A personal health tracker according to Claim 1 further comprising a message [storage means] transmission apparatus by which the subject may create messages and [store them in the data storage unit] transmit them via the communication network.
  
27. (Amended) A method of tracking a medical subject's state of health, the method comprising:
  - periodically and automatically measuring and recording a plurality of different physiological data from a subject with a portable, multiparametric physiological monitoring device, [said different physiological data being pertinent to a plurality of different physiological systems and being collected as an ensemble of measurements taken over time, said ensemble of measurements not being directed to any particular medical condition of the subject but being indicative of a variety of trends in the subject's health such as to describe a general state of health of the subject];
  - tracking the time of recording of the physiological data with a time base;
  - storing the physiological data in a data storage unit with reference to the time base such as to provide a chronological health history of the subject [which covers a period of time that includes time periods during which the subject is in substantially good health and those during which the subject is subject to adverse medical conditions]; [and]
  - collecting subjective data from the subject with a subjective data logger, said data logger being a data input device which records data input

thereto by the subject [and transfers the recorded data to the data storage unit];

connecting directly to a communication network with a data transmission device that allows transmission of collected data to a destination site from points of access to the network that are remote to the destination site; and

locating all of the components of the health tracker together as a portable unit that may be used by an ambulatory patient.

Please add the following new claims:

35. A personal health tracker according to Claim 1 wherein the communication network comprises a data network.
36. A personal health tracker according to Claim 1 wherein the communication network comprises the Internet.
37. A personal health tracker according to Claim 1 wherein the data transmission device comprises a modem.
38. A method according to Claim 27 wherein connecting to a communication network with a data transmission device comprises connecting to a data network with the data transmission device.
39. A method according to Claim 27 wherein connecting to a communication network with a data transmission device comprises connecting to the Internet with the data transmission device.

40. A method according to Claim 27 wherein connecting to a communication network with a data transmission device comprises connecting to a communication network with a modem.
41. A portable personal health tracker comprising:
- a data logger that collects and records subjective data from a subject regarding the subject's psychological condition and subjectively observed physiological condition;
  - a time base which tracks a time of recording of the data;
  - a data storage unit in which the data is stored with reference to the time base such as to provide a chronological health history of the subject; and
  - a data transmission device capable of connecting directly to a communication network to allow transmission of data to a destination site from points of access to the network that are remote to the destination site, wherein each of the components of the health tracker is part of a single, unified portable unit that may be used by an ambulatory patient.
42. A portable personal health tracker according to Claim 41 wherein the data transmission device comprises a modem.
43. A portable personal health tracker according to Claim 41 wherein the data transmission device connects to a data network via a direct telephone connection.
44. A portable personal health tracker according to Claim 41 wherein the data transmission device connects directly to a data network.
45. A portable personal health tracker according to Claim 41 wherein the health tracker is a hand-held device.

46. A portable personal health tracker according to Claim 41 further comprising a message receiver means by which the subject may receive and view messages directed to the data logger.
47. A portable personal health tracker according to Claim 41 further comprising a message generator by which the subject may create and send messages.
48. A portable personal health tracker according to Claim 41 further comprising a tactile input device on which the subject may write and the subject's writing is detected, said tactile input device generating a digitized representation of the detected writing.
49. A portable personal health tracker according to Claim 48 wherein the digitized representation of the subject's writing is transmittable via the data transmission device.
50. A portable personal health tracker comprising:
  - a multiparametric physiological monitoring device which periodically and automatically measures and records from a subject a plurality of different physiological data pertinent to a plurality of different physiological systems;
  - a time base which tracks the time of recording of the physiological data;
  - a data storage unit in which the physiological data is stored with reference to the time base such as to provide a chronological health history of the subject; and
  - a data transmission device capable of connecting directly to a communication network to allow transmission of data to a destination site

from points of access to the network that are remote to the destination site, wherein each of the components of the health tracker is part of a single, unified portable unit that may be used by an ambulatory patient.

51. A portable personal health tracker according to Claim 50 wherein the physiological monitoring device is hand held.
52. A portable personal health tracker according to Claim 50 wherein the physiological monitoring device includes an on-board memory device, and wherein the data storage unit is a database to which the contents of said memory device are uploaded via the data transmission device.
53. A personal health tracking system comprising:
  - a portable unit having a data logger that collects and records subjective data from a subject regarding the subject's psychological condition and subjectively observed physiological condition;
  - a time base of the portable unit which tracks a time of recording of the data;
  - a data storage location remote from the portable unit in which the data is stored with reference to the time base such as to provide a chronological history of the subject's psychological condition; and
  - a data transmission device of the portable unit that transmits data to the data storage location via a digital data network.
54. A personal health tracking system according to Claim 53 further comprising a multiparametric physiological monitoring device of the portable unit that periodically and automatically measures and records from a subject a plurality of different physiological data pertinent to a plurality of different physiological systems.



55. A personal health tracking system according to Claim 53 wherein the digital data network comprises a public data network.
56. A personal health tracking system according to Claim 53 wherein the digital data network comprises the Internet.
57. A personal health tracking system according to Claim 53 wherein the data transmission device comprises a connection device that facilitates connection to the data network.
58. A personal health tracking system according to Claim 57 wherein the connection device comprises a modem that is connectable directly to a public telephone network.
59. A personal health tracking system according to Claim 57 wherein the connection device is connectable directly to a local data network access connection.
60. A personal health tracking system according to Claim 53 wherein the data storage location comprises a digital file server.
61. A personal personal health tracking system comprising:
  - a portable unit having a data logger that collects and records subjective data from a subject regarding the subject's psychological condition and subjectively observed physiological condition;
  - a time base of the portable unit which tracks a time of recording of the data;
  - a data storage location in which the data is stored with reference to the time base such as to provide a chronological history of the subject's psychological condition; and

a tactile input device of the portable unit on which the subject may write and the subject's writing is detected, said tactile input device generating a digitized representation of the detected writing.

62. A personal health tracking system according to Claim 61 wherein the data storage location is remote from the portable unit and the system further comprises a data transmission device of the portable unit that transmits data to the data storage location via a communication network.
63. A personal health tracking system according to Claim 62 wherein the digitized representation of the subject's writing is transmittable via the communication network.
64. A personal health tracking system according to Claim 62 wherein the communication network comprises a digital data network.
65. A personal health tracking system according to Claim 62 wherein the communication network comprises a public telephone network and the portable unit comprises a modem that is connectable directly to the telephone network.
66. A personal health tracking system according to Claim 62 wherein the communication network comprises a digital data network and the portable unit is connectable directly to the data network a local data network access connection.
67. A personal health tracking system according to Claim 66 wherein the data network comprises the Internet.

**REMARKS**

Claim 33 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 33 has been canceled, and it is therefore respectfully requested that this rejection be withdrawn.

Claims 1-10, 20-23, 26-31 and 34 were rejected under the judicially created doctrine of obviousness-type double patenting over Claim 1-17 of U.S. Patent No. 5,778,882. Similarly, Claims 11-19, 24, 25, 32 and 33 were rejected on the same grounds. Claims 11-26 and 32-34 have been canceled, thereby obviated the latter of these two rejections. As to the former, applicants submit that the foregoing claim amendments remove any obviousness between the claims of the present application and those of the earlier patent, and reconsideration of this ground for rejection is respectfully requested. These claim amendments are discussed in more detail below.

Claims 1-9, 20, 26-31 and 34 were rejected under 35 U.S.C. §103(a) as being obvious over Fang et al. '552 ("Fang"). The examiner has stated that Fang discloses a device that allows for the collection of a patient's "psychological" condition. He also states that the Fang patent suggests intermittent operation by making the statement that "the present invention provides a means that shuts down part of the personal health monitor to conserve the battery power yet maintain those features of the personal health monitor essential to monitor for restoration of normal power." The examiner also finds the use of a time base to be obvious because he believes that "the data recorded in Fang would be nonsensical if it were not orderly produced and stored relative to some time frame."

Fang discloses a system for providing power to a personal health monitor in which a backup power source is used in addition to a primary power source. As mentioned by the examiner, the health monitor can measure one or more

clinical parameters. Furthermore, the health monitor can be programmed to present a patient with a series of structured questions to be answered regarding the patient's condition.

In contrast to Fang, the present invention includes a handheld monitor unit that allows it to be easily carried with a subject. A particularly useful feature in this regard is the construction of the monitor to allow direct access to a communications network without requiring connection via a separate unit, such as a personal computer. That is, the monitor is a single, unified handheld unit that includes an on-board communication device, such as a modem. Through this communication device, the handheld unit may be coupled directly to a communication network to allow direct transmission of collected data to a destination site. For example, the handheld unit may have a modem that is simply plugged into a telephone jack. The user, by pressing a single send button, then invokes the transmission protocol of the unit, which includes dialing the number of the destination site, establishing a connection and transmitting the data. There is no need for connecting the device to a computer or otherwise transmitting the data via a secondary control unit.

Claims 20, 26 and 34 have been cancelled. In order to more clearly highlight the advantages of the present invention, Claim 1 has been amended in several ways. Firstly, the claim has been limited to a "handheld" tracker, thereby distinguishing it from those devices which may be movable, but which are not truly ambulatory. By restricting Claim 1 to the term "handheld," it is clear that the claimed invention is a device that can be carried by a patient wherever he or she goes. There is no suggestion in Fang of a truly ambulatory monitor, much less a handheld one.

Claim 1 has also been amended to specify that the handheld device includes a data transmission device that is capable of connecting directly to a

communication network, and that the components of the health tracker, including the data transmission device, are part of a single, unified handheld unit that may be used by an ambulatory patient. Fang has provides no suggestion of a handheld unit, and certainly does not suggest the use of a data transmission device with a handheld unit that allows direct connection from the unit to a communication network. Without such a direct connection capability, a user would have to download the data to a separate processor before it could be transmitted to a remote destination site. This would require the user to carry, in addition to the monitor itself, a portable computer (or other portable processing unit), or to simply wait until he or she reaches a place where a computer with a modem (not to mention the appropriate software) is available.

Claim 27 is a method claim that is similar to Claim 1, and which has been amended in similar ways. Specifically, the method described by Claim 27 now includes the limitation of "connecting directly to a communication network with a data transmission device of the handheld unit." As such, Claim 27 is unsuggested by Fang for the reasons described above with regard to Claim 1. Each of Claims 2-9 depends ultimately from Claim 1, and each of Claims 28-31 depends ultimately from Claim 27. Therefore, each of these dependent claims includes the limitations of Claim 1 or Claim 27 by inheritance, and each is equally unsuggested by Fang. Reconsideration of Claims 1-9 and 27-31 under this ground for rejection is respectfully requested.

Claims 11, 13-16, 19, 24 and 32 were rejected under 35 U.S.C. §103(a) as being obvious over Xu et al. ("Xu"). Each of these claims has been canceled, and this basis for rejection is therefore considered obviated.

In addition to the claim amendments discussed above, applicants have added a number of new claims intended to provide more complete coverage of applicants' invention. New Claims 35-37 depend from Claim 1, and new Claims

38-40 depend from Claim 27, and these claims are therefore considered allowable over the cited prior art for the reasons stated above with regard to those parent claims. New independent Claim 41 is similar to Claim 1, being limited to a single, handheld unit having an data transmission device that connects directly to a communication network, but does not include the limitation of a physiological monitor. Claims 42-49 each depend ultimately from Claim 41. New independent Claim 50 is also similar to Claim 1, but is not limited to a subjective data collection device. Claims 51-52 each depend from Claim 50.

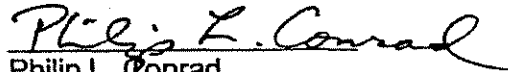
New Claim 53 is also similar to Claim 1, but is limited to a data transmission device that transmits data to a remote data storage location via a digital data network. Also, like Claim 50, Claim 53 is not limited to a physiological monitor. Claims 54-60 each depend ultimately from Claim 53. Finally, new Claim 61 is similar to Claim 53, but is limited to a tactile input device on which a subject using the unit may write, and by which a digitized representation of the subject's writing is created. Claims 62-67 each depend ultimately from Claim 61.

Acceptance and allowance of applicants' new claims is respectfully requested. Some additional claim amendments not described above have been made for clarification purposes, or to allow the amended claim to better agree with other amendments.

In light of the foregoing amendments and remarks, it is respectfully requested that all the claims be allowed such that the application may be passed to issue. If it is believed that a telephone conference will help expedite prosecution of the application, the examiner is invited to call the undersigned.

The Commissioner is hereby authorized to charge any additional fees due for the filing of this paper to applicants' attorneys' Deposit Account No. 02-3038.

Respectfully submitted,



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